

## **REMARKS**

### **Status of the Claims**

Claims 1 and 22-28 are pending in the present application. Claims 2-21 were previously canceled. In further response to the Office Action dated May 15, 2009, Applicants submit herewith the following remarks and Supplemental Declaration under 37 C.F.R. § 1.132. Reconsideration is respectfully requested.

### **Issues Under 35 U.S.C. § 112, First Paragraph, Enablement**

Claims 1-8 and 14-21 were rejected under 35 U.S.C. § 112, first paragraph, in the Office Action of May 15, 2009, as allegedly failing to comply with the enablement requirement, *see* May 15, 2009, Office Action, pages 6-12. Specifically, the Examiner alleged that the correlation of polymorphisms and phenotypes is unpredictable, *see* Office Action, pages 10-11.

In the response submitted to the USPTO on November 16, 2009, Applicants argued that the polymorphisms specified in the instant claims may be predictably linked to drug sensitivity. In support thereof, Applicants submitted the Ikeda Declaration, which noted that the present application teaches that the polymorphism at position IVS3+A615G is significantly associated with methamphetamine sensitivity. The Ikeda Declaration further stated that IVS3+A615G is in strong linkage disequilibrium with IVS3+A8449G. Accordingly, an ordinary artisan would have recognized that IVS3+A8449G is also associated with drug sensitivity. In support thereof, the Ikeda Declaration provided further data that confirmed that IVS3+8449G is associated with 24 hour postoperative fentanyl use.

In further support of Applicants' November 16, 2009, arguments, submitted herewith is the Ikeda Supplemental Declaration. The Ikeda Supplemental Declaration provides additional data, which demonstrate that IVS3+A6151G is not only associated with methamphetamine use, but is also associated with 24 hour postoperative fentanyl use. Accordingly, in view of the teachings in the present application, as well as the arguments and data provided to the USPTO on November 16, 2009, and the Ikeda Supplemental Declaration submitted herewith, an ordinary artisan could have reasonably predicted that the polymorphisms described in the instant

application are associated with drug sensitivity. Based upon the foregoing, the claims comply with the enablement requirement. Withdrawal of the rejection is respectfully requested.

### CONCLUSION

In view of the above remarks and Supplemental Declaration under 37 C.F.R. § 1.132, submitted herewith, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact L. Parker, Reg. No. 46,046, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: DEC 1 2009

Respectfully submitted,

By 

Marc S. Weiner  
Registration No.: 32,181  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Enclosure: Supplemental Declaration under 37 C.F.R. § 1.132